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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,460	08/04/2003	William J. Ayala	2006-0191	4666

7590 01/04/2008

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EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
01/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/633,460	AYALA, WILLIAM J.	
	Examiner	Art Unit	
	Melissa Perreira	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *8/4/03* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/12/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/12/07 has been entered.

Status of the Claims and previous rejections

2. Claims 39-61 are pending in the application. Claim 61 is newly added in the amendment filed 10/12/07. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated. Applicant's assertion that none of the prior art references either singularly or in combination teach or suggest such a sleep regulating pharmaceutical formulation is moot in view of the new grounds of rejection.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 39-43,47-54,57 and 58 are rejected under 35 U.S.C. 102(e) as being anticipated by Jaenicke et al. (US 6,458,384B2).

5. Jaenicke et al. (US 6,458,384B2) teaches a sleep pharmaceutical formulation that comprises a sedative or soporific agents/first component (i.e. valerian, melatonin, benzodiazepines) for immediate release and a core/second component (i.e. caffeine, modafinil) for delayed release via coating (column 5, lines 30-36; column 7, line 28; column 11, lines 19-22,37-42 and 63-65). The delaying coating surrounds the core/core granules (plurality of pellets) containing the second component and may be cellulose acetate (column 13, line 67; column 17, example 2; column 21, lines 35-36). Other excipients, such as citric acid, calcium carbonate, etc. may be included in the formulations (column 8, lines 36 and 57).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 39-43 and 47-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jaenicke et al. (US 6,458,384B2) in view of Baker (US 3,952,741) or Rashid (US 6,200,600B1).

8. Jaenicke et al. (US 6,458,384B2) discloses a sleep pharmaceutical formulation that comprises a sedative or soporific agents/first component (i.e. valerian, melatonin, benzodiazepines) for immediate release and a core/second component (i.e. caffeine, modafinil) for delayed release via a coating (column 5, lines 30-36; column 7, line 28; column 11, lines 19-22,37-42 and 63-65). The delaying coating surrounds the core/core granules (plurality of pellets) containing the second component and may be cellulose acetate (column 13, line 67; column 17, example 2; column 21, lines 35-36). Other excipients, such as citric acid, calcium carbonate, etc. may be included in the formulations (column 8, lines 36 and 57). Also, the formulations may be manufactured into any well known galenic formulation, such as swelling/erosion controlled; breakage/fracture controlled, etc. (column 7, lines 65+). Jaenicke et al. does not explicitly disclose a weak spot or seam.

9. Baker (US 3,952,741) discloses an osmotic dispenser for administration of an active agent to humans at a controlled rate over a prolonged period of time that allows for treating pathological conditions of the living body (column 1, lines 58-59; column 3, lines 61-64). The osmotic device is enclosed in a semi-permeable membrane which is impermeable to the active agent but is permeable to water and that allows for a delay between the time of administration to the time of bursting while inhibiting the tendency of the active agent to leach (column 3, lines 49-55; column 4, lines 4-6). The design of

the osmotic dispenser includes that where a plurality of said dispensers can release active agent as a single pulse or as several discrete pulses via a coating (column 3, 65-68). To control this delay a thicker coating or a different material may be applied, such as cellulose acetate, cellulose nitrate or polyvinyl alcohol, as well as those listed in the instant claims (column 4, lines 19-22; column 5, lines 32-39). Figure 2 shows the osmotic dispenser incorporating a seam or a weak spot (figure 3.) and rupturing may occur along this seam or weak spot (column 4, lines 47-52).

10. Rashid (US 6,200,600B1) discloses an oral dosage form of a control release capsule comprising a water permeable cellulose acetate, cellulose nitrate, etc., where the controlled release of active material may be over the period before and or after the sharp pulsed release of material and the delay time is from 4-8 hr (column 1, lines 27-33; column 2, lines 17-20) The dosage form contains a hole that is drilled into the capsule from the exterior to the interior and filled with active material as well as inert excipients, such as gas releasing material (claim 29, column 3, lines 1-9; 16-26 and 46-48; column 6, line 28). The drugs utilized in this device are sedatives and tranquilizers (column 4, lines 31-32).

11. At the time of the invention it would have been obvious to one ordinarily skilled in the art to use the tablet systems of Jaenicke et al. (e.g. with a combination of release systems and pharmaceutically active substances) along with the weakened inner core via a seam disclosed by Baker or hole disclosed by Rashid. Jaenicke et al. does disclose breakage/fracture controlled galenic formulations and therefore the results of including such a hole or seam would give predictable results, such as the calculated

release of the inner substance depending on the weakened portion of the inner semi-permeable coating. The delay coating of the disclosure encompasses the instant claims and therefore if would be obvious to utilize similar release techniques and since the coating does not dissolve in gastric fluids it is obvious that in order to have a shorter delay time one must weaken the membrane to expedite release of the active substance.

12. Claims 39-54 and 57-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jaenicke et al. (US 6,458,384B2) in view of Chopinet-Cote et al. (EP 1074249A1).

13. Jaenicke et al. (US 6,458,384B2) discloses a sleep pharmaceutical formulation that comprises a sedative or soporific agents/first component (i.e. valerian, melatonin, benzodiazepines) for immediate release and a core/second component (i.e. caffeine, modafinil) for delayed release via a coating (column 5, lines 30-36; column 7, line 28; column 11, lines 19-22,37-42 and 63-65). The delaying coating surrounds the core/core granules (plurality of pellets) containing the second component and may be cellulose acetate (column 13, line 67; column 17, example 2; column 21, lines 35-36). Other excipients, such as citric acid, calcium carbonate, etc. may be included in the formulations (column 8, lines 36 and 57). Also, the formulations may be manufactured into any well known galenic formulation, such as swelling/erosion controlled; breakage/fracture controlled, etc. (column 7, lines 65+). Jaenicke et al. does not explicitly disclose the gas generating substance and acid are included in the inner subsystem.

14. Chopinet-Cote et al. (EP 1074249A1) discloses a tablet system having a core-centered body covered with adjacent layers, one element fully enclosing the other (abstract). The enclosed elements (coating) have active substance while the enclosing element is devoid of active substance and delays the release of the latter by a no-release period. The enclosing element has an intrinsic porosity that will remain constant while allowing aqueous medium to penetrate and thus a rapid release of active substance (abstract; p4, [0020] and [0026]; p5, [0027]). The enclosed element comes into contact with aqueous medium through the porous coating and is altered in volume due to swelling allowing for a rapid release of the core active agent (p5, [0033]). The oral delivery tablet system for pharmaceutical use is capable of releasing an active substance/first component during a release period of predetermined duration and quantity of active agent followed by a no-release period devoid of active substance then a subsequent release period of an active material/second component having a predetermined release rate (p2, [0003]; p4, [0019]) by controlling the amount of retarding (no-release) layer, such as cellulose acetate and others listed in the instant claims the lag time can be 3 h up to 6 or 7 h (for a natural effect of nocturnal rest (p6, [0040]; p 19, [0124] and [0126]) (p4, [0018]). Degradation of the enclosed element (i.e. core) will cause a swelling (i.e. osmotic device) or effervescence which causes the enclosing element to become fragmented (p4, [0021-0022]) via excipients, such as sodium hydrogen carbonate and citric acid contained in the core (p6, [0039]). Figure 2 provides a schematic of the tablet system comprising a core with active substance, an intermediate layer devoid of active substance and an external coating layer with active

substance (p8, [0052]) while figure 3 contains those described in figure 2 and an external coating layer (p9, [0059]). The tablet system may be comprised of a plurality of couples of tablet elements (p4, [0025]).

15. At the time of the invention it would have been obvious to one ordinarily skilled in the art to use the tablet systems of Jaenicke et al. (e.g. with a combination of release systems and pharmaceutically active substances) along with the rapid release/effervescent tablet formulation of Chopinet-Cote et al. to allow for the release of an active substance/first component during a release period of predetermined duration and quantity of active agent followed by a no-release period devoid of active substance then a subsequent release period of an active material/second component having a predetermined release rate. Jaenicke et al. does disclose breakage/fracture controlled galenic formulations and therefore the results of including an effervescent compound would give predictable results, such as the calculated release of the inner substance depending on the inner semi-permeable coating. The delay coating of the disclosure encompasses the instant claims and therefore if would be obvious to utilize similar release techniques and since the coating does not dissolve in gastric fluids it is obvious that in order to have a shorter delay time one must weaken the membrane to expedite release of the active substance.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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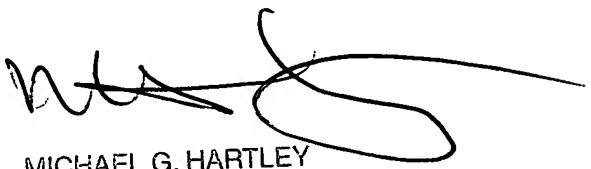
December 21, 2007



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SUPERVISORY PATENT EXAMINER